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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

JAZZ PHARMACEUTICALS, INC. and JAZZ PHARMACEUTICALS IRELAND LIMITED **Plaintiffs,** **v.** **RANBAXY LABORATORIES LIMITED and RANBAXY INC.,** **Defendants.**	**Civil Action No. _____** **COMPLAINT FOR PATENT INFRINGEMENT** **(Filed Electronically)**

Plaintiffs Jazz Pharmaceuticals, Inc. and Jazz Pharmaceuticals Ireland Limited (collectively, "Jazz Pharmaceuticals"), by their undersigned attorneys, for its Complaint against defendants Ranbaxy Laboratories Limited and Ranbaxy Inc. (collectively, "Ranbaxy"), allege as follows:

Nature of the Action

1. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. §100, *et seq.*, arising from Ranbaxy's filing of an Abbreviated New Drug Application ("ANDA") with the United States Food and Drug Administration ("FDA") seeking approval to commercially market a generic version of Jazz Pharmaceuticals' XYREM® drug

product prior to the expiration of United States Patent Nos. 8,772,306 (the "'306 patent" or "the patent-in-suit") owned by Jazz Pharmaceuticals.

The Parties

2. Plaintiff Jazz Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 3180 Porter Drive, Palo Alto, California 94304.

3. Plaintiff Jazz Pharmaceuticals Ireland Limited is a corporation organized and existing under the laws of Ireland, having a principal place of business at One Burlington Road, Fourth Floor, Connaught House, Dublin, Ireland 4.

4. On information and belief, Defendant Ranbaxy Laboratories Limited is a company organized and existing under the laws of India, having a principal place of business at 12th Floor, Devika Towers, 6 Nehru Place, New Delhi, India.

5. On information and belief, Defendant Ranbaxy Laboratories Limited regularly transacts business within this judicial district. On information and belief, Ranbaxy Laboratories Limited develops numerous generic drugs for sale and use throughout the United States, including in this judicial district. On information and belief, Ranbaxy Laboratories Limited also prepares and/or aids in the preparation and submission of ANDAs to the FDA.

6. On information and belief, Defendant Ranbaxy Inc. is a company organized and existing under the laws of the State of Delaware, having a principal place of business at 600 College Road East, Princeton, New Jersey 08540.

7. On information and belief, Defendant Ranbaxy Inc. regularly conducts business in this judicial district, including marketing and selling pharmaceutical products. Further, on information and belief, Ranbaxy Inc. is an authorized agent for Ranbaxy Laboratories Limited, and a wholly-owned subsidiary of Ranbaxy Laboratories Limited.

8. On information and belief, Defendant Ranbaxy Laboratories Limited and Ranbaxy Inc. acted collaboratively in the preparation and submission of ANDA No. 203351 to the FDA. On information and belief, Ranbaxy Laboratories Limited's submission of ANDA No. 203351 to the FDA was done at the direction, under the control, and for the direct benefit of Ranbaxy Inc.

9. On information and belief, following any FDA approval of ANDA No. 203351, Defendants Ranbaxy Laboratories Limited and Ranbaxy Inc. will work in concert with one another to make, use, offer to sell, and/or sell the generic products that are the subject of ANDA No. 203351 throughout the United States, and/or import such generic products into the United States.

Jurisdiction and Venue

10. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

11. This Court has personal jurisdiction over Ranbaxy Laboratories Limited by virtue of, inter alia, its systematic and continuous contacts with the State of New Jersey. On information and belief, Ranbaxy Laboratories Limited has purposefully availed itself of this forum by, among other things, making, shipping, using, offering to sell or selling, or causing others to use, offer to sell, or sell, pharmaceutical products in the State of New Jersey and deriving revenue from such activities. Further, on information and belief, Ranbaxy Laboratories Limited has customers in the State of New Jersey.

12. This Court has personal jurisdiction over Ranbaxy Inc. by virtue of, *inter alia,* its systematic and continuous contacts with the State of New Jersey. On information and belief, Ranbaxy Inc. has its principal place of business in Princeton, New Jersey, conducts business in this District, purposefully avails itself of this forum by, among other things, making, shipping,

using, offering to sell or selling, or causing others to use, offer to sell, or sell, pharmaceutical products in the State of New Jersey and deriving revenue from such activities. Also, on information and belief, Ranbaxy Inc. has customers in the State of New Jersey. Further, on information and belief, Ranbaxy Inc. is registered to conduct business in the State of New Jersey.

13. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391 and 1400(b).

The Patent-In-Suit

14. On July 8, 2014, the United States Patent and Trademark Office ("USPTO") duly and lawfully issued the '306 patent, entitled "Method of Administration of Gamma Hydroxybutyrate with Monocarboxylate Transporters." A copy of the '306 patent is attached hereto as Exhibit A.

The XYREM® Drug Product

15. Jazz Pharmaceuticals holds an approved New Drug Application ("NDA") under Section 505(a) of the Federal Food Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. § 355(a), for sodium oxybate oral solution (NDA No. 21-196), which it sells under the trade name XYREM®. The claims of the '306 patent cover, *inter alia*, methods for treating patients suffering excessive daytime sleepiness, cataplexy, sleep paralysis, apnea, narcolepsy sleep time disturbances, hypnagogic hallucinations, sleep arousal, insomnia and nocturnal myoclonus with GHB or a salt thereof by orally administering an adjusted dosage amount of the salt of GHB when the patient is receiving concomitant administration of valproate. Jazz Pharmaceuticals owns the '306 patent.

16. Pursuant to 21 U.S.C. § 355(b)(1) and attendant FDA regulations, the '306 patent is listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to XYREM®.

17. The labeling for XYREM® instructs and encourages physicians, other healthcare workers, and patients to administer XYREM® according to the methods claimed in the '306 patent.

Acts Giving Rise to This Suit

18. Pursuant to Section 505 of the FFDCA, Ranbaxy filed ANDA No. 203351 ("Ranbaxy's ANDA") seeking approval to engage in the commercial use, manufacture, sale, offer for sale or importation of 500 mg/mL sodium oxybate oral solution ("Ranbaxy's Proposed Product"), before the patent-in-suit expires.

19. On information and belief, in connection with the filing of its ANDA as described in the preceding paragraph, Ranbaxy has provided a written certification to the FDA, as called for by Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Ranbaxy's Paragraph IV Certification"), alleging that the claims of the '306 patent are invalid, unenforceable, and/or will not be infringed by the activities described in Ranbaxy's ANDA.

20. No earlier than August 20, 2014, Jazz Pharmaceuticals received written notice of Ranbaxy's Paragraph IV Certification ("Ranbaxy's Notice Letter") pursuant to 21 U.S.C. § 355(j)(2)(B) concerning the '306 patent. Ranbaxy's Notice Letter alleged that the claims of '306 patent are invalid, unenforceable, and/or will not be infringed by the activities described in Ranbaxy's ANDA. Ranbaxy's Notice Letter also informed Jazz Pharmaceuticals that Ranbaxy seeks approval to market Ranbaxy's Proposed Product before the patent-in-suit expires.

21. On information and belief, Ranbaxy has not submitted a statement to the FDA pursuant to 21 U.S.C. § 355(j)(2)(A)(viii) that Ranbaxy seeks to market its Proposed Product for a use other than that claimed in the patent-in-suit.

22. Under applicable laws and regulations, the FDA will not approve Ranbaxy's Proposed Product with labeling that does not include information regarding dose modification in patients receiving concomitant administration of sodium oxybate and valproate that is necessary for the safe and effective use of sodium oxybate.

Count I: Infringement of the '306 Patent

23. Plaintiffs repeat and reallege the allegations of paragraphs 1-22 as though fully set forth herein.

24. Ranbaxy's submission of its ANDA to obtain approval to engage in the commercial use, manufacture, sale, offer for sale, or importation of sodium oxybate oral solution, prior to the expiration of the '306 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

25. There is a justiciable controversy between the parties hereto as to the infringement of the '306 patent.

26. Unless enjoined by this Court, upon FDA approval of Ranbaxy's ANDA, Ranbaxy will infringe the '306 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing, and/or selling Ranbaxy's Proposed Product in the United States.

27. Unless enjoined by this Court, upon FDA approval of Ranbaxy's ANDA, Ranbaxy will induce infringement of the '306 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, importing, and/or selling Ranbaxy's Proposed Product in the United States. On information and belief, upon FDA approval of Ranbaxy's ANDA, Ranbaxy will intentionally encourage acts of direct infringement with knowledge of the '306 patent and knowledge that its acts are encouraging infringement.

28. Unless enjoined by this Court, upon FDA approval of Ranbaxy's ANDA, Ranbaxy will contributorily infringe the '306 patent under 35 U.S.C. § 271(c) by making, using,

offering to sell, importing, and/or selling Ranbaxy's Proposed Product in the United States. On information and belief, Ranbaxy has had and continues to have knowledge that Ranbaxy's Proposed Product is especially adapted for a use that infringes the '306 patent and that there is no substantial non-infringing use for Ranbaxy's Proposed Product.

29. Jazz Pharmaceuticals will be substantially and irreparably damaged and harmed if Ranbaxy's infringement of the '306 patent is not enjoined.

30. Jazz Pharmaceuticals does not have an adequate remedy at law.

31. This case is an exceptional one, and Jazz Pharmaceuticals is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

(A) A Judgment be entered that Ranbaxy has infringed the patent-in-suit by submitting ANDA No. 203351;

(B) A Judgment be entered that Ranbaxy has infringed, and that Ranbaxy's making, using, selling, offering to sell, or importing Ranbaxy's Proposed Product will infringe one or more claims of the patent-in-suit;

(C) An Order that the effective date of FDA approval of ANDA No. 203351 be a date which is not earlier than the later of the expiration of the patent-in-suit, or any later expiration of exclusivity to which Plaintiffs are or become entitled;

(D) Preliminary and permanent injunctions enjoining Ranbaxy and its officers, agents, attorneys and employees, and those acting in privity or concert with them, from making, using, selling, offering to sell, or importing Ranbaxy's Proposed Product until after the expiration of the patent-in-suit, or any later expiration of exclusivity to which Plaintiffs are or become entitled;

(E) A permanent injunction be issued, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Ranbaxy, its officers, agents, attorneys and employees, and those acting in privity or concert with them, from practicing any methods as claimed in the patent-in-suit, or from actively inducing or contributing to the infringement of any claim of the patent-in-suit, until after the expiration of the patent-in-suit, or any later expiration of exclusivity to which Plaintiffs are or become entitled;

(F) A Declaration that the commercial manufacture, use, importation into the United States, sale, or offer for sale of Ranbaxy's Proposed Product will directly infringe, induce and/or contribute to infringement of the patent-in-suit;

(G) To the extent that Ranbaxy has committed any acts with respect to the compositions and methods claimed in the patent-in-suit, other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), that Plaintiffs be awarded damages for such acts;

(H) If Ranbaxy engages in the commercial manufacture, use, importation into the United States, sale, or offer for sale of Ranbaxy's Proposed Product prior to the expiration of the patent-in-suit, a Judgment awarding damages to Plaintiffs resulting from such infringement, together with interest;

(I) Attorneys' fees in this action as an exceptional case pursuant to 35 U.S.C. § 285;

(J) Costs and expenses in this action; and

(K) Such further and other relief as this Court may deem just and proper.

Dated: October 2, 2014

By: s/ Charles M. Lizza

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CERTIFICATION PURSUANT TO L. CIV. R. 11.2

I hereby certify that the matters captioned *Jazz Pharmaceuticals, Inc. v. Roxane Laboratories, Inc.*, Civil Action No. 10-6108 (ES)(MAH), *Jazz Pharmaceuticals, Inc. v. Amneal Pharmaceuticals, LLC*, Civil Action No. 13-391 (ES)(JAD), *Jazz Pharmaceuticals, Inc. v. Ranbaxy Laboratories Ltd., et al.*, Civil Action No. 14-4467 (ES)(JAD), and *Jazz Pharmaceuticals, Inc. v. Par Pharmaceutical, Inc.*, Civil Action No. 14-5139 (ES)(JAD) are related to the matter in controversy because the matter in controversy involves defendants who filed Abbreviated New Drug Applications seeking to market generic versions of the same drug product.

I further certify that, to the best of my knowledge, the matter in controversy is not the subject of any other action pending in any court or of any pending arbitration or administrative proceeding.

Dated: October 2, 2014

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